UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,835	08/04/2003	Tedd E. Elich	9280.2	5061

20792 7590 04/11/2007
MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER
BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/633,835	ELICH ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12,13 and 16-25* is/are pending in the application.

4a) Of the above claim(s) *4-7, 9 and 16-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 3, 8, 10 ,12 , 13 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. In view of applicant's request to withdraw Finality of Rejections Under M.P § 706.07(d) on November 14, 2006, the finality of the Office action 10/13/06 is withdrawn .

2. Applicant's, amendment filed on 1/11/07 is acknowledged and entered. Accordingly , the examiner is issuing a non- final rejection .

Status of Claims

3. Claims 1-10, 12, 13 and 16-25 are pending in this application.

Claims 6, 9, 12 and 22 have been amended

New claims 23-25 have been added .

Claims 1, 2, 3, 8, 10 ,12 , 13 and 23-25 are under examination with respect to SEQ.ID.NO: 2.

Claims 4-7, 9 and 16-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non elected inventions.

New Claim Rejections - 35 USC 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 2, 3, 10 ,12 , 13 and 23-25 are rejected under 35 USC 112, first paragraph, as lacking an adequate written description in the specification.

Claims 1, 2, 3, 10 ,12 , 13 and 23-25 are drawn to a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase domain, wherein said peptide binds to soraphen, said peptide is a monomer and has a soraphen dissociation constant of from 10^{-7}-10^{-14}, wherein said ACCase is selected from the group consisting of mammal, insect, yeast, Ascomycota, Basidiomycota, and Oomycota ACCase, wherein said carboxylase is Ustilago maydis carboxylase Or a peptide consisting essentially of a functional Acetyl CoA carboxylase (ACCase) biotin carboxylase domain, wherein said functional biotin carboxylase domain binds to soraphen , wherein said ACCase is selected from the group consisting of mammal, insect, yeast, Ascomycota, Basidiomycota, and Oomycota ACCase, wherein said carboxylase is Ustilago maydis carboxylase. These claims are directed to a genus of a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase domain, wherein said peptide binds to soraphen. The specification teaches the structure of only a single representative species of a peptide consisting of Acetyl CoA carboxylase (ACCase) biotin carboxylase domain, SEQ.ID.NO:2, wherein said functional biotin carboxylase domain binds to soraphen. Moreover, the specification fails to describe any

other representative species by any identifying characteristics or properties. Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. Thus, the instant specification may provide an adequate written description of the a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase that binds to soraphen from the group consisting of mammal, insect, yeast,

Ascomycota, Basidiomycota, and Oomycota ACCase or a peptide consisting essentially of a functional Acetyl CoA carboxylase (ACCase) biotin carboxylase domain, wherein said functional biotin carboxylase domain binds to soraphen , wherein said ACCase is selected from the group consisting of mammal, insect, yeast, Ascomycota, Basidiomycota, and Oomycota ACCase, per Lilly by structurally describing a representative number of "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase that binds to soraphen or a peptide consisting essentially of a functional Acetyl CoA carboxylase (ACCase) biotin carboxylase domain, in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase that binds to soraphen or a peptide consisting essentially of a functional Acetyl CoA carboxylase (ACCase) biotin carboxylase domain,, nor does the specification provide any partial structure of such a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase that binds to soraphen or a peptide consisting essentially of a functional Acetyl CoA carboxylase (ACCase) biotin carboxylase domain,, nor any physical or chemical characteristics nor any functional characteristics coupled with a known or disclosed correlation between structure and function. Although the specification discloses a single peptide consisting of Acetyl CoA carboxylase (ACCase) biotin carboxylase domain, SEQ.ID.NO:2, wherein said functional biotin carboxylase domain binds to soraphen, this does not provide a description of a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase that binds to soraphen or a peptide consisting essentially of a functional Acetyl CoA carboxylase (ACCase) biotin carboxylase domain, that would satisfy the standard set out in Enzo.

The specification also fails to describe a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase that binds to soraphen or a peptide consisting essentially of a functional Acetyl CoA carboxylase (ACCase) biotin carboxylase domain by the test set out in Lilly. The specification describes only a single peptide consisting of Acetyl CoA carboxylase (ACCase) biotin carboxylase domain, SEQ.ID.NO:2. Therefore, it necessarily fails to describe a "representative number" of such

species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, the specification does not provide an adequate written description of a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase that binds to soraphen or a peptide consisting essentially of a functional Acetyl CoA carboxylase (ACCase) biotin carboxylase domain that is required to practice the claimed invention. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention

Claim Rejections - 35 USC 102 maintained

6. The rejection of claims 1 -3 , 10 , 12 and 23-25 under 35 U.S.C. 102(b) as being anticipated by Bailey et al Mol Gen Genet (1995) 249: 191-201(IDS 11/17/03) is maintained for the same reasons as set forth in the previous office action.

Applicant argues 1/11/07 that Bailey et al reference describes a small portion of the coding region found in the BC domain of the ACCase gene of U. maydis (Figure 2) and was not concerned with actually obtaining a peptide comprising a portion of the BC domain that binds to soraphen. Applicant provides the crystal structure of the yeast BC domain that binds to soraphen, and the amino acids that interact with soraphen . In Shen et al., (2004) " Molecular Cell, 16:881-891 (enclosed with this Response), the inventors, along with their collaborators at Columbia University, reported the crystal structures of the yeast BC domain, alone and in complex with soraphen. Figure 1 on page 882 shows the residues involved in soraphen binding, highlighted in the figure in green. The deduced amino acid sequence in Bailey et al corresponds to amino acids 257-325 of the yeast sequence reported in Shen et al as demonstrated by the following amino acid sequence alignment.

The argument has been considered but found to be non-persuasive because the claims do not set forth any structural details of a peptide that binds to soraphen. Further , applicant has provided an amino acid sequence that is involved in soraphen binding (Figure 1 on page 882 shows the residues involved in soraphen binding). However, the rejected claims do not contain amino acid residues that are involved in soraphen binding. In the absence of such structural details the art reads on the claimed invention.

7. The rejection of claims 1-2, 10 , 12 and 23-24 under 35 U.S.C. 102(b) as being anticipated by Schulte et al 1997 Proc. Natl. Acad. Sci. USA Vol. 94, pp. 3465-3470 is maintained for the same reasons as set forth in the previous office action.

Applicant states 1/11/07 that as an initial matter, the examiner treated election of SEQ ID: 2 as an election of species.

The examiner would like to bring applicant's attention to restriction requirement and the non-final office action mailed on 12/12/06 and 5/9/06 respectively. It is specifically noted, that a species election was not imposed. Each of the recited sequences were deemed patentably distinct from each other and applicants were required to elect a single product for examination on the merits. As such, examination of the single product is restricted to the SEQ ID NO:2.

Applicant argues that the examiner indicated the pertinent art that related to other species and therefore, election of SEQ.ID.NO:2 is not limited to the Ustilago ACCase.

The argument has been considered but found to be non-persuasive because the claims are rejected based on the art but not based on the Election. Applicant admits on record that Schulte et al show a "[d]endrogram based on a comparison of deduced amino acid sequences covering the BC domains or BC subunits from ACCases of different organisms" .

Applicant argues that A1-Feel et al reported the gene having a putative Biotin Binding ("Biotin Binding Site") and a Carboxytransferase ("Transcarboxylase") domain. Therefore, A1-Feel did not teach of an ACCase having a deleted Biotin Binding domain and deleted Carboxytransferase domain.

The argument has been considered found to be non-persuasive because the examiner rejected the claims based on Schulte et al 1997 not based on A1-Feel.

8. The rejection of claims 1 -3 , 10 , 12, 13 and 23-25 under 35 U.S.C. § 103(a) as being unpatentable over Bailey or Schulte et al and each in view of Trubetskoy et al U.S.Patent 7,098,032 is maintained for the same reasons as set forth in the previous office action.

Applicant sates the Bailey or Schulte et al do not read on the claimed invention , therefore, the 103 rejection should be withdrawn.

The argument has been considered found to be non-persuasive because Bailey or Schulte et al have been discussed and the rejections have been maintained as set forth above.

Remarks

9. No claims are allowed.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP ' 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

10 Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Jeffery Siew can be reached on (571) 272-0787. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER